Exhibit B

MEDICAL DEVICE DESIGNER'S WORKBENCH

BRIEF SUMMARY OF THE INVENTION

Medical procedure simulators are currently used to train surgeons and health professionals in performance of various medical procedures. This use of simulators improves the skill of medical practitioners without putting patients at risk, since procedures can be practiced safely until a minimum level of skill is attained before procedures are performed on actual patients.

An heretofore undeveloped extension of this technology is to use the systems to improve the design process for medical devices. Particularly in the field of minimally invasive procedures, the design of new devices and evaluation of their performance in actual use is made more difficult by the remote control nature of the procedures, and the separation of the practitioner from the actual site of the procedure. Evaluation and prediction of the efficacy of various combinations of materials, material properties, shapes, and interactions is difficult if not impossible without actually performing procedures on actual patients, or more typically animals. Additional means of evaluation and prediction would possibly speed and improve the development process. Endovascular procedures such as balloon angioplasty, stent placement, and heart pacing leads placement are a few of the procedures that might benefit from a richer set of design tools. In

OBJECTS AND FEATURES

Provide a method for engineers to predict the efficacy of new designs in the presence of a range of anatomical variations.

Enable users, e.g. surgeons and other medical practitioners to participate in the design process, whereby their superior knowledge of anatomy and physiology can be complemented with engineering knowledge embodied in the simulation system.

An additional object of the system is to facilitate communication between medical practitioners, engineers, designers and others. The system enables users to modify devices without knowledge of device mechanics and demonstrate increased utility of the device. Functions as a sort of "electronic cocktail napkin" in the design process.

BRIEF DESCRIPTION OF THE DRAWINGS

DETAILED DESCRIPTION OF THE INVENTION

Modes of Operation

Simulation based design

In this mode, a skilled practitioner or other user attempts a procedure using a simulation system simulating use of a particular tool, such as wire or catheter, with physical parameters such as shape, stiffness, torsional rigidity, and the like that can be varied along the length of the device, or in response to temperature, time or some other method or means. The user is presented with materials views and editors in which the various properties can be varied to evaluate their effects on the ease of execution or the procedure, or the effect on procedural outcomes. For example, the viewer and editor for a stylet used to steer a heart pacing lead might consist of a graphical display of a model of the wire, with materials properties at various points along the wire represented accompanying line or bar graphs, or directly on the wire itself by means of color or other graphical means. A modal editor is used to modify parameters along the length or the device. The editor allows the user to specify which parameter or parameter is being altered, then enables setting values for that parameter at particular points along the length of the device. The editor can optionally interpolate materials properties between user set points, or can be used in full manual mode. Parameters that can be set at any point along the length of the device would include but not be limited to the following:

* Rest angle, angle of bend
* Stiffness, resistance to bending
* Torsional rigidity, resistance to twisting
* Viscosity or ductility
* Frictional characteristics, smoothness, roughness
* Temperature or time varying behavior

The practitioner would use the editors to modify the device in advance or and during the simulated procedure, observing the efficacy of various modifications and thus greatly speeding the design process.

In addition to the device editors, the practitioner would be provided with anatomical editors, allowing simulation of a wider range of anatomical variation. An electrical and physical model of the heart muscle,

for instance, is used to provide a normal anatomy in which to manipulate devices. Modifications to the anatomy can be made in real time to simulate various anamolies. Valve defects, arrythmia, necrotic tissue, etc. can all be edited by the user to provide a wide range of variability of anatomical situations.

- Cad Import
o interface to FEA
o materials properties
o Simple version (utility 8, difficulty 2 - just match our properties editor's inputs)

Goal directed simulation

In this mode, the user defines a goal for the medical procedure and then uses the simulation in an automatic mode to try to reach the goal without violating key constraints. For example, in the case of a patient with particularly tortuous venous or arterial anatomy, navigating a stent into place via a delivery catheter can be difficult or impossible to accomplish without modifying the catheter or choosing a smaller stent. To design a delivery catheter that suits a wider range of anatomy, the workbench software can select a variety of anatomical types from a data store, then determine how successful a skilled practitioner would be using a particular device. Device parameters can be modified, either by the simulation system, or by a skilled practitioner or engineer, and the simulation can be rerun to evaluate the effectiveness of the modifications in terms of anticipated procedure outcomes.

It is noted that in a procedure with "n" degrees of freedom the current state of the procedure can be characterized as a position in "n-space" defined by the coordinates of the individual degrees of freedom. When an additional parameter, time, is added, the entire procedure can be characterized as a connected series of positions in the "nspace" consisting of the n degrees of freedom plus time. Thus one path through the n dimensional state space exists for each possible procedure. Corresponding to each point or step along the procedure path are the physiological effects and consequences resulting from that step. The overall outcome of the procedure can be characterized by examination and summarization of the physiological effects caused along the path of the procedure.

Method
* Select anatomy from database, customize if desired
* Select device parameters, customize if desired (automated or manual)
* Begin simulation

o Automatically "explore" envelope of possible actions given the particular degrees of freedom available to practitioner (e.g. for a steerable catheter, insertion, rotation, tip flexion, and the like would all be available)
* Randomly select a particular action from the range of actions available for each degree of freedom, then execute a time step of the simulation and evaluate the results of the time step with respect to the overall goal as well as the constraints (i.e. evaluate progress towards goal as well as possible damage to tissues and other physiological effects)
* Store results of the time step, reset to the beginning of the time step, and repeat the random selection and time step
* After a statistically significant number of time steps have been simulated, rank order the results of the time step in terms of effectiveness metrics, then exclude those which exceed permissible values, and characterize the "envelope" of acceptable maneuvers to this point in the simulation.
o Repeat the process for additional steps in the procedure, where possible reducing similar paths (paths that produce similar results) to a single path.
o Report overall outcome in terms of medical significance, e.g. reaching goal position, minimizing side effects
o Repeat anatomy and device selection steps, repeat simulation

In a variant of the goal directed simulation, an expert system can be used to drive the simulation in seeking the goal, or a genetic algorithm can be used to steer and maneuver the lead into position, learning along the way optimum ways of maneuvering to reach the goal.

After a set of simulations has been run, an examination of the irreducible minimum physiological side effects can be used to reshape or change materials of the tool or portion of the tool or tools and the simulation can be rerun.

In another variation of the goal directed simulation, the practitioner provides constraints on the path the simulation system should attempt to maneuver. Using a three dimensional model and computer drawing tools, the designer constrains or otherwise identifies the desired final position and permissible path (or portions of the path) that the device may follow when being navigated into place. This speeds the convergence of the simulation process.

Computer observation of practitioner

In another mode of design, a skilled practitioner uses the simulation, trying to achieve the goals of the procedure. The simulation system automatically observes and records the user's manipulation of the simulated medical device or devices to learn what they do in particular situations. The system characterizes the practitioner's maneuvers and extracts knowledge that the practitioner might not

otherwise be able to articulate of otherwise recognize or communicate to others. The resulting model of a given practitioner's skills, competencies, abilities, and range of maneuvers they can successfully perform can be analyzed for implications in device design and competency training.

Super slow speed simulation

- Simulation validity
o Ideally simulators represent "perfect" physics
o Fast time sims make some compromises - their range of validation is thus limited - perfect physics might be too slow
o Can we run sims in slow motion where necessary to get physics more nearly perfect? What about interactions?
o Interact with a partially validated model at fast speeds, then via playback (of actions or intentions?) at slow speed in slow, valid simulation, validate the overall efficacy of the fast sim
o Record the slow sim and play back at fast speed

Ideally simulators represent physics and physiological models that have been shown to be sufficiently accurate for the purposes for which they are used. These simulators are said to be validated for the particular use. Real time simulations sometimes make compromises that limit their validity for uses beyond training, such as for device design. In the situation where an adequately accurate simulation of the physics or physiological effects of the system is so demanding of the simulation systems resources that it cannot run fast enough to operate in real time, the simulation cannot be used with human operators, because they cannot reliably and accurately slow their own interactions to match the speed of the simulation. In this case, the operator can interact with a partially validated simulation to prove the efficacy of a design, and then use the automation guided, goal directed simulation to simulate actions of the human operator in the non-real time simulation, thus enabling a more accurate simulation of the procedure to be exercised, both enabling validation of the real time simulation, as well as extending the capabilities of the simulation system into areas that could not otherwise be simulated.

Custom devices

Using patient specific data in a pre-operative rehearsal, the practitioner can design or develop the optimum catheter or tool for a particular patient. This is the extension of mass customization to medical devices and extends the current practice of manually bending and otherwise shaping a lead in advance of the procedure.

Life testing

The simulation system can be used to perform simulated device life testing, identifying points of stress and strain both on the device as well as on the simulated anatomy. It can thus be used to predict failures such as device materials failures, failures to maintain proper position in the anatomy, and adverse physiological reactions such as scarring or perforation of tissues.

Additional material - not to be included.

Tools

Design Automation

Optimum shape when implanted in a given position.. e.g. wear and tear on heart muscle,

- Optimum shape to reach a given point

o

o A "helper" application determines the best static shape to fit the region - given all the "states" the device must transition through while being navigated into place - make both static and dynamic versions (beating heart)

o The helper application may use

* artificial intelligence

* Monte Carlo simulation

* Or other techniques to mimic possible surgeon navigation techniques

o Produce a parametric "envelop" of shapes and materials properties

o (torsional rigidity, compliance, etc.) that would work well

o

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Displays

o

- Outputs - production of prototype devices
o Stereolith for catheters - "extrude to design" - produce the designed catheter for evaluation quickly

- Evaluation of devices
o Analysis of effect of tortuous anatomy
o Forces, range of anatomy to which a device is applicable

- Pacing efficiency
o validated electrical model of heart
o "sensitivity analysis" of location

- Possible initial test bed
o Heart model/editor
o Electrical
o Pacing efficacy
o Wire Editor - bending (no 3d initially)
o Materials editor - bending moments variable over length of lead

- Heart

o materials properties
o shape
* shapes from toolbox 7/4
* algorithmic changes (e.g. chamber sizes parametrically adjusted - heart motion mods) 7/4
* Total freedom (i.e. Bill) 7/9
o electrical
o flaws
o regional
o valve defects
o flow
o "Condition based editing - e.g. infarction

o coded display of property vs length

- Toolbox of anatomies
o normal
o tortuous

- Cad import
o interface to FEA
o materials properties
o Simple version (utility 8, difficulty 2 - just match our properties editor's inputs)

Value 0-9 low/high
Difficulty 0-9 easy to hard

Issues
- validation
- "competition" with FEA engineers
- total market
- other compensation

Outputs (views)
- static shape in a vessel (editable vessel?) Gary's model 8/3
- Forces experienced in the heard during the procedure
- Color coded surface model or statistics max, avg, number of hits, etc. 8/4
- Replay of a procedure